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EXAMINER

KIM, CHONG R

ART UNIT

PAPER NUMBER

2623

DATE MAILED: 07/29/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,325

Applicant(s)

EVIRON ET AL.

Examiner

Charles Kim

Art Unit

2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: typographical errors. The phrase “meteorological tools” in the applicant’s specification appears to have been spelled incorrectly. It appears that the applicant intended the phrase to read “metrological tools”. Appropriate correction is required.

2. A substitute specification including the textual specification and the claims is required pursuant to 37 CFR 1.125(a) because the current specification is missing page numbers.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Objections

3. Claim 4 is objected to because the phrase “meterological measurements” in line 2 appears to have been spelled incorrectly. It appears that the applicant intended the phrase to read “metrological measurements”. Appropriate correction is required.

Art Unit: 2623

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claim 1, the phrase “determine from the three-dimensional reconstruction of the arterial tree at least one perspective of the artery perpendicular to the axis of the artery, and generate a three dimensional reconstruction of the artery from angiographic images obtained essentially from the determined at least one perspective” in lines 9-14 is not sufficiently supported in the applicant’s specification. More specifically, it appears that the applicant’s specification fails to provide support in the case where one perspective perpendicular to the axis of the artery is obtained to generate a three dimensional reconstruction of the artery. The only support found in the applicant’s specification states “the microprocessor then calculates two or more perspectives perpendicular to the axis of the selected artery”. Therefore, it appears that the applicant’s specification provides support in regards to “at least two perspectives” perpendicular to the axis of the artery, but fails to provide support for “at least one perspective”, as claimed.

Art Unit: 2623

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5-6, 8-10, 12-13, 15, 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al., U.S. Patent No. 6,047,080 ("Chen").

Referring to claim 1, Chen discloses a system for imaging an artery contained in an arterial tree, the artery having an axis, comprising a microprocessor configured to:

- a. generate a three-dimensional reconstruction of the arterial tree from two angiographic images of the arterial tree obtained from different perspectives (col. 4, lines 41-67)
- b. determine an orientation of the axis of the artery in the arterial tree (col. 4, lines 56-58 and col. 16, line 64-67)
- c. determine from the three-dimensional reconstruction of the arterial tree at least one perspective of the artery perpendicular to the axis of the artery (col. 17, lines 29-32)
- d. generate a three dimensional reconstruction of the artery from angiographic images obtained essentially from the determined at least one perspective [col. 17, lines 29-37.

Chen explains that the three-dimensional reconstruction of the arterial tree is represented by a sequence of perspectives (cross-sectional contours) perpendicular to the axis of the artery. The Examiner notes that a three-dimensional reconstruction of the artery obtained from at least one

Art Unit: 2623

determined perspective is inherent in Chen's three-dimensional reconstruction of the arterial tree, since the three-dimensional reconstruction of the arterial tree includes the three-dimensional reconstruction of the artery, wherein the three-dimensional reconstruction of the artery is obtained from a sequence of perspectives (cross-sectional contours), as noted above].

Referring to claim 2, Chen discloses that the microprocessor is further configured to display on a display the reconstruction of the arterial tree (col. 17, lines 34-37).

Referring to claim 3, Chen further discloses a display configured to display the reconstruction of the arterial tree (col. 18, lines 31-38. Note that a display is inherent in the "3-D computer" used to view the reconstruction of the arterial tree).

Referring to claim 5, see the rejection of at least claim 3 above. Chen discloses that the microprocessor is further configured to manipulate an image on the display (col. 18, lines 31-38).

Referring to claim 6, see the rejection of at least claim 3 above. Chen further discloses that the microprocessor is configured to display on the display a view of the three-dimensional reconstruction of the arterial tree from a selected perspective (col. 18, lines 31-38).

Referring to claim 8, see the rejection of at least claim 6 above. The Examiner notes that displaying the three-dimensional reconstruction of the arterial tree will inherently display the three-dimensional reconstruction of the artery embedded in the three-dimensional display of the arterial tree, since the artery is included in the arterial tree, as noted above.

Referring to claims 9, 20 and 21, see the rejection of at least claim 1 above.

Referring to claim 10, see the rejection of at least claim 2 above.

Referring to claim 12, see the rejection of at least claim 5 above.

Referring to claim 13, see the rejection of at least claim 6 above.

Art Unit: 2623

Referring to claim 15, see the rejection of at least claim 8 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 7, 11, 14, 16-18, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., U.S. Patent No. 6,047,080 ("Chen"), further in view of the article entitled "Assessment of Diffuse Coronary Artery Disease by Quantitative Analysis of Coronary Morphology Based upon 3-D Reconstruction from Biplane Angiograms" by Wahle et al. ("Wahle").

Referring to claim 4, Chen does not explicitly state that the microprocessor is configured to make metrological measurements on the reconstruction of the arterial tree. However, making meterological measurements on a reconstruction of an arterial tree was exceedingly well known in the art. For example, Wahle teaches the step of making meterological measurements (quantitative assessment) on a three-dimensional reconstruction of an arterial tree (pages 237-238, section labeled "B. Methods").

Chen and Wahle are both concerned with analyzing three-dimensional reconstructions of an arterial tree. Chen explains that his system is utilized for clinical use (Chen, col. 18, lines 31-36). Wahle explains that coronary artery disease is a major epidemiological problem, and

Art Unit: 2623

provides a system that improves the diagnosis of coronary artery diseases such as diffuse disease by quantitative analysis of the three-dimensional reconstructions of an arterial tree (page 230 and 237). Therefore, it would have been obvious to modify the processor of Chen so that it is configured to make meterological measurements on the reconstruction of the arterial tree, as taught by Wahle, in order to contribute to the advancement in the medical/clinical field by enhancing the diagnosis of coronary artery diseases.

Referring to claim 7, see the discussion of at least claim 6 above. The Examiner notes that displaying a view of the three-dimensional reconstruction of the arterial tree will inherently display a view of the three-dimensional reconstruction of the artery, since the artery is included in the arterial tree, as noted above. Chen explains that the three-dimensional reconstruction of the artery is displayed from a selected perspective (view), wherein the reconstructed artery is represented by cross-sectional contours (col. 17, lines 20-30 and col. 18, lines 31-38). Chen further explains that the reconstructed artery can be viewed at any perspective, in order to determine which perspectives are useful for clinical use (col. 18, lines 31-36). However, Chen does not explicitly teach the step of viewing the three-dimensional reconstruction of the artery from a cross sectional perspective.

Wahle teaches that a cross sectional perspective of a three-dimensional reconstruction of an artery is useful for clinical use for diagnosing coronary artery diseases (page 237, section labeled "A. Overview"). Therefore, it would have been obvious to modify the perspective of Chen so that is a cross sectional perspective, as taught by Wahle, in order utilize the perspective for clinical use, thereby enhancing the diagnosis of coronary artery disease.

Referring to claim 11, see the rejection of at least claim 4 above.

Art Unit: 2623

Referring to claim 14, see the rejection of at least claim 7 above.

Referring to claim 16, Chen discloses a method for displaying an arterial tree in an individual for clinical use comprising:

- a. generating a three-dimensional reconstruction of the arterial tree from two angiographic images of the arterial tree obtained from different perspectives (col. 4, lines 41-67)
- b. determining an orientation of the axis of the artery in the arterial tree (col. 4, lines 56-58 and col. 16, line 64-67)
- c. determine from the three-dimensional reconstruction of the arterial tree at least one perspective of the artery perpendicular to the axis of the artery (col. 17, lines 29-32)
- d. generate a three dimensional reconstruction of the artery from angiographic images obtained essentially from the determined at least one perspective [col. 17, lines 29-37. Chen explains that the three-dimensional reconstruction of the arterial tree is represented by a sequence of perspectives (cross-sectional contours) perpendicular to the axis of the artery. The Examiner notes that a three-dimensional reconstruction of the artery obtained from at least one determined perspective is inherent in Chen's three-dimensional reconstruction of the arterial tree, since the three-dimensional reconstruction of the arterial tree includes the three-dimensional reconstruction of the artery, wherein the three-dimensional reconstruction of the artery is obtained from a sequence of perspectives (cross-sectional contours), as noted above],
- e. analyzing the three-dimensional reconstruction of the artery (col. 18, lines 31-38).

Chen explains that his method is used for clinical use, but fails to teach that it used for diagnosing stenosis. Wahle teaches that the three dimensional reconstruction of an arterial tree can be used for diagnosing stenosis (page 237, section labeled "B. Methods").

Art Unit: 2623

Chen also fails to teach the step of detecting a stenotic artery in the three-dimensional reconstruction of the arterial tree. Wahle teaches the step of detecting a stenotic artery in the three-dimensional reconstruction of the arterial tree [pages 237-240. Note that the artery detected in the three-dimensional reconstruction of the arterial tree for the patients with severe diffuse and dilating coronary artery disease (DCAD) is a stenotic artery].

Chen and Wahle are both concerned with analyzing three-dimensional reconstructions of an arterial tree. Chen explains that his system is utilized for clinical use (Chen, col. 18, lines 31-36). Wahle explains that coronary artery disease is a major epidemiological problem, and provides a system that improves the diagnosis of stenosis by analyzing the three-dimensional reconstructions of an arterial tree (page 230 and 237). Therefore, it would have been obvious to modify the method of Chen so that it is used for diagnosing stenosis, and includes the step of detecting a stenotic artery in the three-dimensional reconstruction of the arterial tree, as taught by Wahle, in order to contribute to the advancement in the medical/clinical field by enhancing the diagnosis of coronary artery diseases.

Referring to claim 17, see the rejection of at least claim 16 above. Chen does not explicitly teach that the step of analyzing the three-dimensional reconstruction of the artery includes determining the length of the stenosis in the stenotic artery.

Wahle teaches the step of analyzing the three-dimensional reconstruction of the artery that includes determining the length of the stenosis in the stenotic artery (page 238, left column). Therefore, it would have been obvious to modify the analyzing step of Chen so that it includes determining the length of the stenosis in the stenotic artery, as taught by Wahle, for the reasons stated above.

Art Unit: 2623

Referring to claim 18, Chen further discloses that the arterial tree is a coronary arterial tree (col. 18, lines 31-32).

Referring to claims 22-23, see the rejection of at least claim 16 above.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., U.S. Patent No. 6,047,080 ("Chen"), in view of the article entitled "Assessment of Diffuse Coronary Artery Disease by Quantitative Analysis of Coronary Morphology Based upon 3-D Reconstruction from Biplane Angiograms" by Wahle et al. ("Wahle"), further in view of applicant's admitted prior art ("Admission").

Referring to claim 19, see the discussion of at least claim 16 above. Chen further discloses that the artery has a lumen (col. 6, lines 12-15), and the lumen has a cross-section of maximal narrowing (col. 8, lines 11-20. Note that the "minimum vessel diameter" is interpreted as the lumen with a cross-section of maximal narrowing).

Chen fails to teach a stenotic artery that has a fraction of the artery occluded by plaque. Wahle teaches a stenotic artery, as noted above, wherein the stenotic artery has a fraction occluded by plaque (page 237, section labeled "B. Methods").

Chen and Wahle both fail to teach that determining the severity of the stenosis includes determining the fraction of the cross-section of the maximal narrowing occluded by plaque.

Admission teaches that it was well known to determine the severity of the stenosis by determining the fraction of the cross-sectional area of the lumen that is occluded by plaque (section labeled "BACKGROUND OF THE INVENTION" in the applicant's specification).

Art Unit: 2623

Chen, Wahle and Admission are all concerned with analyzing three-dimensional reconstructions of an arterial tree. Therefore, it would have been obvious to modify the method of Chen and Wahle, so that the severity of the stenosis is determined by determining the fraction of the cross-section of the maximal narrowing occluded by plaque, as taught by Admission, in order to enhance the diagnosis of coronary artery diseases.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Carroll et al. U.S. Patent No. 6,501,848 discloses a method for three-dimensional reconstruction of an arterial tree that allows a user to select an artery in the arterial tree.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Monday thru Thursday 8:30am to 6:00pm and alternating Fridays 9:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Art Unit: 2623

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0377.

ck

ck

July 28, 2003


Jon Chang
Primary Examiner